

# NIH Legislative Update

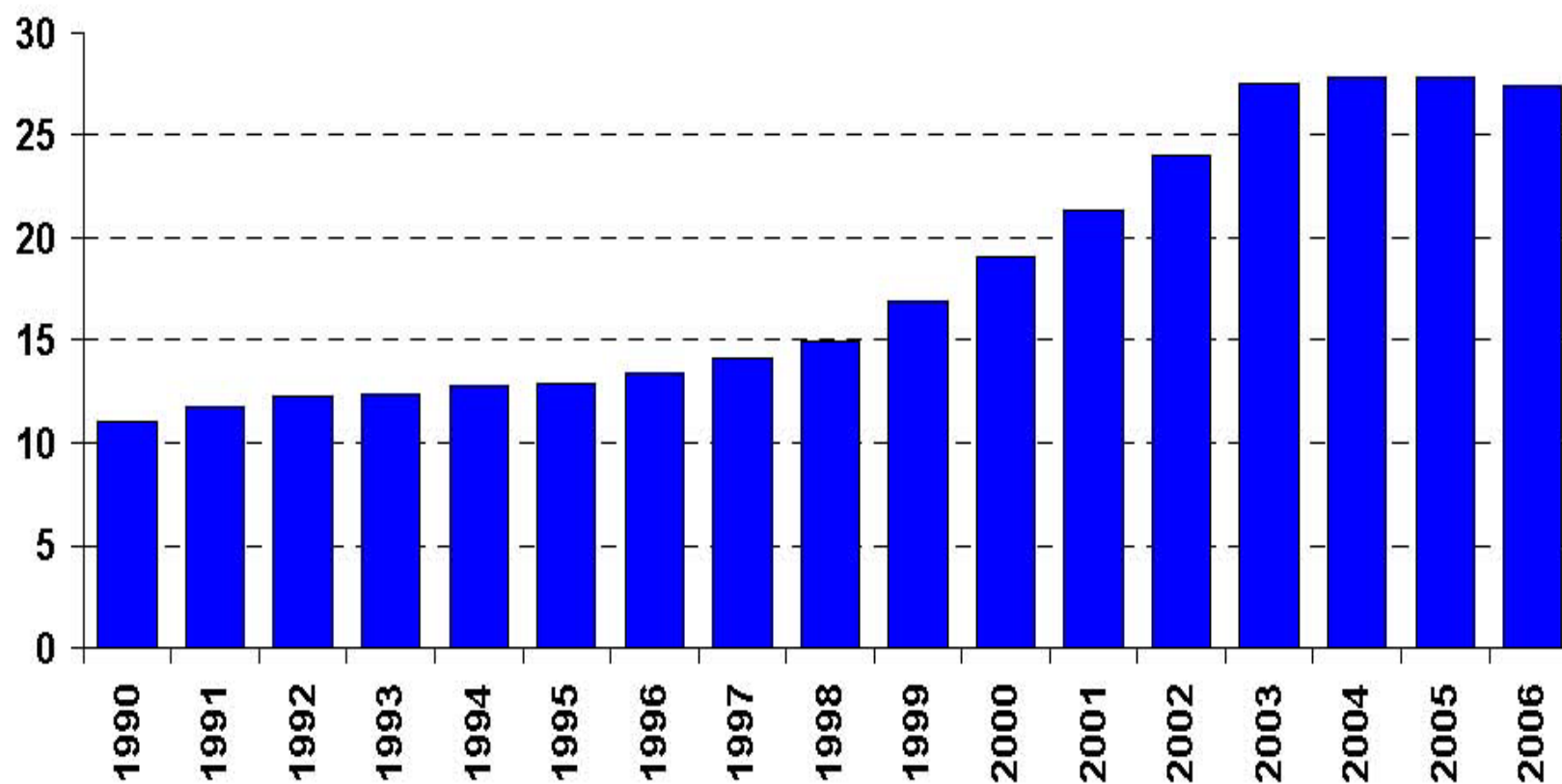
Presented to the Advisory  
Committee to the Director

December 2, 2005



## Trends in NIH R&D, FY 1990-2006

in billions of constant FY 2005 dollars



# Status of 2006 Appropriations

FY 2005  
\$27.8 B

FY2006 Request  
\$27.9 B

FY2006 Conf.  
\$28 B

Conference number represents .3% increase, smallest since 1970.

Conference agreement defeated in House. Senate instructs conferees to renegotiate higher number for NIH.

Conference reconvenes Dec. 12-13.





# The PHS Act of 1944



## Mission of NIH

Section 301 of the PHS Act – “The Secretary shall conduct in the Service and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man . . .”



# Reauthorization Process

- Authorization bills must be introduced by Member of Congress, but can emanate from various sources.
- Programs are authorized for a specific time period, usually 3 year cycles.
- Programs can continue without being reauthorized if funds are appropriated.
- At any time, Congress may make amendments to, and authorizations for, existing programs.
- Congress may also add prohibitions and requirements, at will.
- Authorization process has been subsumed by appropriations process.
- House and Senate rules allow circumvention of standard legislative process.



# The Committees

- **House Committee on Energy and Commerce**
  - Joe Barton, R-TX, Chairman
  - John Dingell, D-MI, Ranking Member
- **Senate Committee on Health, Education, Labor and Pensions (HELP )**
  - Michael Enzi, R-WY, Chairman
  - Edward Kennedy, D-MA, Ranking Member





# Chronology

- Nine hearings between June 6, 2002 and July 19, 2005.
- Joint House/Senate survey of NIH stakeholders in 2002.
- IOM report, 2002.
- Committee staff interviews 23 IC Directors in April and June 2004.
- First draft bill circulated July 12, 2005.
- Second draft bill circulated August 22, 2005.
- Stakeholders meeting August 25, 2005.



## **Congressional Concerns**

- NIH Has Not Adequately Explained How It Sets Priorities
- Research Priorities Are Unbalanced, Reflected By Investments In Sexuality Studies And Other Inappropriate Research
- NIH Is Unable To Fund Collaborative Research
- NIH Is Unable To Quickly Respond To New Public Health Priorities By Shifting Resources
- NIH Priorities Are Set By Institute Directors And Not The Director of NIH





# **The Sole Driving Force**

**Joe Barton, Chairman**  
**House Energy and Commerce Committee**



# The Chairman's Objectives

- **Restore Committee's Purview.**
- **Expand Authority of NIH Director to improve portfolio management and facilitate trans-NIH research.**
- **Realign budget authorities to foster collaboration.**
- **Streamline and improve public reporting of research results.**



## **Key Provisions of August 22 Draft Legislation**

- Creation of two budget categories for ICs (definition being revised to denote equality between categories).
- Budget authorization ceiling (unspecified).
- Limit on number of ICs.
- Restatement of existing reorganization authorities, with added requirement for public hearings.
- Creation of program coordination unit within OD, with IC input and advisory body review.



## **Key Provisions, continued**

- Creation of Common Fund set aside.
- Director receives approval authority over future Centers of Excellence.
- Clarification of hiring authority under Title 42 (needs further revision).
- Affirmation of existing IC statutory authorities.
- Requires establishment of uniform electronic coding system.
- Biennial reports required (needs to be refined).
- Bridging the sciences demonstration project.
- Increase in support of FNIH.





## Implications

- Program coordination provisions will bring rigor to research collaboration process and provide a mandatory funding mechanism.
- Categorization of ICs into budget categories does not create any legal changes to existing appropriations process.
- Signals end of structural growth at NIH for near future.
- No changes in base authorities, including general investigative powers, peer review and intramural program.
- No policy implications, including stem cells, behavioral research or disease specific directives.



## **Dr. Zerhouni's Response**

- Cites OPASI as important new tool.
- Agrees that there should be more flexibility in how NIH allocates its budget, including enhanced authority for the Director.
- Agrees that current structure of NIH creates priority-setting difficulties across the Agency.
- Cites need for cross-cutting research.





## **Preserving the Heart of NIH's Authority**

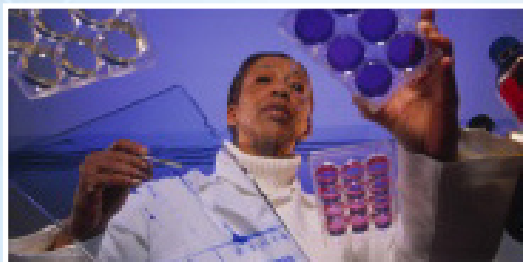
- Maintain current peer review process
- Maintain emphasis on investigator-initiated research
- Continue policy of minimal congressional directives
- Maintain general research authorities
- Enhance scientific freedom



## Forecast

- Appropriation restrictions big obstacle.
- Lack of stakeholder interest.
- Not a priority for Congressional leadership.
- Reauthorization tacitly opposed by Administration.
- Final passage unlikely this year.





# NIH

Ideas  
People  
Resources  
Leadership

